

Remarks

Claims 17-26 and 29-46 were pending in the subject application. Applicants acknowledge that claims 30 and 31 have been withdrawn from consideration as being drawn to non-elected species. By this Amendment, claims 17, 34, and 44 have been amended, claims 19, 25, 26, 30, and 31 have been cancelled, and new claim 47 has been added. Support for the new claim and amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 17, 18, 20-26, 29, and 32-46 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Claims 17-26, 29, and 32-46 are rejected under 35 USC §112, first paragraph, as non-enabled by the subject specification. Under this rejection, the Examiner seems to suggest that the claims are not enabled for *ex vivo* gene therapy. The Examiner also asserts that the claims are only enabled for use with heart cells because the elected species of promoter (MCL-2v) would not function in non-heart cells. Applicants respectfully assert that the claims are enabled by the subject specification. The subject specification does enable *ex vivo* gene therapy. As noted by the Examiner, the subject specification teaches introducing a vector into stem cells and transplantation of the cells back into the host. For example, cells can be injected directly back into the target tissue via intra-pericardial injection or intracardiac intravenous delivery. Moreover, Applicants note that the level of skill in the art is high. Thus, a person of ordinary skill in the art can readily practice the claimed invention. In addition, claim 17 has been amended to specify that the target tissue is cardiac tissue. Thus, the elected species of promoter would function in cardiac tissue and cells. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claim 44 is rejected under 35 USC §112, second paragraph, as indefinite. Applicants respectfully assert that the claim is definite. Applicants respectfully submit that the claim is clear in its recitation that two elements are co-administered in the claimed method: i) stem cells and ii) an agent that effects migration of the cells to the target tissue. The agent can be different than the composition of claim 17 comprising the first and second polynucleotides. Accordingly,

reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 17-22, 24-26, and 32-46 remain rejected under 35 USC §103(a) as obvious over Peterson *et al.* (U.S. Patent Publication No. 2002/0094327) in view of Phillips *et al.* (2002) and in further view of Tang *et al.* (2002a). Claims 17, 23, and 44 remain rejected under 35 USC §103(a) as obvious over Peterson *et al.* in view of Phillips *et al.* and Tang *et al.* (2002a), and further in view of Kovesdi *et al.* (U.S. Patent Publication No. 2003/0027751). In addition, claims 17-22, 24-26, 29-43, 45, and 46 are rejected under 35 USC §103(a) as obvious over Peterson *et al.* in view of Tang *et al.* (2002b). Claims 17, 23, and 44 are rejected under 35 USC §103(a) as obvious over Peterson *et al.* in view of Tang *et al.* (2002b) and further in view of Kovesdi *et al.* Applicants respectfully traverse these grounds of rejection. Applicants respectfully submit that the cited references, taken alone or in combination, do not teach or suggest the claimed invention.

As an initial matter, the Examiner indicates that Applicants' arguments regarding the lack of a publication by Peterson *et al.* or others teaching the claimed invention do not negate the obviousness of combining the cited references. However, Applicants respectfully submit that it is evidence, along with other evidence to be considered in totality, as to the non-obviousness of Applicants' claimed invention.

Applicants respectfully assert that, prior to the subject invention, the claimed methods were not obvious to a person of ordinary skill in the art. The Examiner essentially takes the position that it would have been obvious to combine the teachings of the Peterson *et al.* reference with the Phillips *et al.* and Tang *et al.* references and thereby arrive at Applicants' claimed invention. Applicants respectfully assert that there was no motivation or suggestion to combine the teachings of the cited references. Moreover, there would not have been a reasonable expectation of success in arriving at Applicants' claimed invention for the reasons Applicants have indicated previously. Arriving at the claimed invention required more than simply substituting therapeutic genes with chemokine genes as suggested by the Examiner. By this Amendment, Applicants have amended claim 17 to recite that the target tissue is damaged or at risk of damage, and that the claimed method results in reduced damage or reduced risk of damage. The cited references do not teach or suggest that damage to the target tissue could be reduced or repaired.

As the Examiner is aware, in order to support a *prima facie* case of obviousness, a person of ordinary skill in the art must generally find both the suggestion of the claimed invention, and a reasonable expectation of success in making that invention, solely in light of the teachings of the prior art and from the general knowledge in the art. *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion, nor the reasonable expectation of success, of Applicants' claimed invention in the cited references.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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